UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,313	09/24/2001	Gunther Berndl	0050/49860	8414

26474 7590 10/23/2006

NOVAK DRUCE DELUCA & QUIGG, LLP
1300 EYE STREET NW
SUITE 400 EAST TOWER
WASHINGTON, DC 20005

EXAMINER	
YOUNG, MICAH PAUL	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,313	BERNDL ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-12 and 14-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-12 and 14-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Response dated 8/2/06.

Election/Restrictions

1. Newly submitted claim 28 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claim is drawn to a process for making an excipient comprising spray drying or extrusion, where the extrusion process comprises a liquid oil. However the extrusion process is recited as an alternative and not a requirement of the claim.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 28 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 10-12,14,17-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Ball et al (UPSN 6,063,865 hereafter '865) and Guzi, Jr. et al (USPN 4,127,422 hereafter '422). The claims are drawn to a process for making an excipient comprising spray drying a solution comprising a water-soluble N-vinylpyrrolidone polymer and a surface-active agent.

2. The '865 patent discloses a process for making a free-flowing excipient carrier comprising a water-soluble polymer and other ingredients (abstract, col. 2, lin. 1-4). The excipient includes anion and ionic surfactants along with polyvinylpyrrolidones with K-values from 10-120 (col. 4, lin. 58-63; col. 6, lin. 4-18). The composition is spray-dried and atomized into a powder (col. 6, lin. 38-46). Additives for the composition further include dyes and emulsifiers (col. 6, lin. 62-67). The carrier is not a pigment. The particle size of the excipient is up to 10 microns (col. 6, lin. 35). The reference is however silent to the inclusion of the specific ranges of the surfactants or their respective HLB values.

3. The '422 patent discloses a process for making dry polymer compound comprising polymer of N-vinyl pyrrolidone and a surfactant (abstract, col. 3, lin. 5-15), where a solution comprising the polymers is spray-dried (claim 2). The surfactant can be nonionic and can have ab HLB from 11-18 and is present in a concentration from 14-45% (col. 3, lin. 10-11, lin. 33-42). The N-vinyl pyrrolidone has a K value between 15 and 21 (example 7). The formulation further comprises other polymers such as starches, gums, and cellulose derivatives, all of which are useful as flow regulator agents, bulking agents and tableting excipients (col. 5, lin. 9-19). The

formulation also comprises a pigment (examples). An artisan would have been motivated to include the surfactants of the '422 into the '865 process in order to ease production and reduction of the particles.

4. Regarding the limitations of claims 14 and 17, reciting the specific concentrations of surfactant in the excipient, it is the position of the examiner that such limitations do not impart patentability in view of the prior art. The '422 patent discloses a process for making an excipient comprising polyvinylpyrrolidone, and a surfactant, where the solution is spray-dried. The general conditions of the limitations are met by these disclosures. It is the position of the examiner that the determination of these rages is well within the level of ordinary skill in the art and can be determined through routine experimentation. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

5. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

6. Regarding claim 11, it is the position of the examiner the drop point would be inherent to any surfactant with the appropriate HLB and solubility. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and

functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

7. With these things in mind it would have been obvious to follow the suggestions of the '865 reference and include the surfactants of the '422 reference into the process in order to produce a dry excipient comprising a vinylpyrrolidone polymer and a nonionic surface-active agent by spray drying. A skilled artisan would have been motivated to optimize the concentrations and ranges of the reference in order to provide a superior excipient product. It would have been obvious to skilled artisan to follow these teachings with an expected result of a spray-dried excipient with improved stability.

8. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Ball et al (UPSN 6,063,865 hereafter '865), Shih et al (USPN 6,011,096 hereafter '096); and Sutton et al (USPN 5,993,805 hereafter '805). The claims are drawn to a process for making an excipient comprising spray drying a solution comprising a water-soluble N-vinylpyrrolidone polymer and a surface-active agent.

9. As discussed above the '865 reference discloses a process for making an excipient comprising a polymer of N-vinylpyrrolidone and a surface active agent, where a solution of the polymers is spray-dried. The '865 reference discloses such surfactants as oleates and polyglycolic ethers (col. 6, lin. 4-18), yet is silent to the specific surfactant of claims 15 and 16.

However the inclusion of specific components that have an established equivalency is well within the level of skill in the art, as seen in the '096 and '805 references.

10. The '096 patent discloses a composition comprising polyvinylpyrrolidone with a K value between 12 to 120 and emulsifier surfactants such as lauryl alcohol polyether, oleates and polyethoxylated sorbitan (col. 2, lin. 12-20, col. 3, lin. 8). The small particles recovered from the suspension are of a higher purity (col. 2, lin. 38-46). A skilled artisan would have been motivated to combine the surfactant of '096 into the formulation and process of '865 since they both combine water-soluble emulsifiers.

11. The '805 patent discloses a spray-dried microparticle formulation comprising water-soluble hydrophilic compounds such as polyvinylpyrrolidone (col. 7, lin. 44), and surface-active agents such as glycerol polyoxyethylene rinoleate, polyoxypropylene glycol and polyoxyethylene glycol (col. 7, lin. 58-63). These compounds are similar to those of the '865 and would be within the level of skill in the art to substitute into that formulation.

12. With these things in mind it would have been obvious to a skilled artisan to combine the teachings and suggestions of the art. A skilled artisan would have been motivated to combine the surfactants of '096 into the process of '865, under its suggestions to improve the purity and stability. A skilled artisan would have been motivated to include the combine the surfactant of '805 into the process of '865, under its suggestions in order to improve the stability of the formulation. It would have been obvious to a skilled artisan to combine the teachings and suggestions as such with an expected result of a spray-dried excipient with improved stability and purity.

Response to Arguments

13. Applicant's arguments filed 8/2/06 have been fully considered but they are not persuasive. Applicant argues that:

a. There is no motivation to combine the teachings of Ball with those of Guzi, or any of the supporting references.

14. Regarding this argument it is the position of the Examiner that the '865 reference taken in combination with the '422 patent obviate the instant claims. The '865 patent discloses a free flowing polymer excipient comprising homo or copolymers of vinylpyrrolidone. The vinylpyrrolidone has a k-value from 10-120, and the excipient is formed via spray drying. The reference is silent however to the specific surfactants in use and their respective HLB values. The artisan would be motivated tot include the surfactants of the '422 in order to ease the processing and particle size reduction. Though the surfactants are present in the '865 formulation, the reference is silent to their concentration or HLB values. For this information the artisan of ordinary skill would be motivated to look to the '422 patent. The '422 patent discloses an excipient formulation comprising homo and copolymers of vinylpyrrolidone and 15-45% of non-ionic surfactants. The ionic surfactants are identical to those used in the '865 patent. The '422 patent discloses that the concentration must be within this range for optimal ease of processing and size reduction. It would have been obvious to include these concentrations of well-known surfactants into the formulation of the '865 with an expected result of an excipient that was easy to produce and reduce to a desired size.

15. Barring evidence to the contrary, it is the position of the Examiner that the combined disclosures render the claims obviated. Applicant argues that the Guzi reference is drawn to a

pigment and as such cannot obviate the claims. However the Examiner is not relying on the pigment disclosures of Guzi to obviate the claims. The Guzi reference is relied upon for its disclosures of non-ionic surfactants and their use in particle production. As discussed above the Guzi reference is relied upon to supply the deficiency of the '865 patent and therefore combine obviates the instant claims. With these aspects in mind the claims remain obviated by the combined disclosures of the '865 patent in view of the '422 patent.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618

MP Young

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER